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Use of Magnesium Alloys in Tension Band Wiring of Olecranon Fractures

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USE OF MAGNESIUM ALLOYS IN TENSION BAND WIRING OF OLECRANON FRACTURES

A Major Qualifying Project Report Submitted to the Faculty of the
WORCESTER POLYTECHNIC INSTITUTE

In partial fulfillment of the requirements for the
Degree of Bachelor of Science
in Mechanical Engineering

Submitted by:

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1. Olecranon Fractures
2. Magnesium Alloys
3. Bioabsorbable Implants
4. Finite Element Analysis

Abstract

Fractures of the olecranon are common elbow injuries that represent about 10% of upper extremity lesions. Tension band wiring is a surgical technique to fix olecranon fractures. This technique involves inserting two pins and a tension band wire in a figure eight configuration to convert the tensile forces affecting the fracture into compressive forces. After the bone is healed, the hardware is no longer necessary and is typically removed through a second surgery in response to the pain and discomfort it causes. Currently, the pins and wires are primarily made of 316L stainless steel. Magnesium alloys have recently been recognized for their potential use in orthopedic applications requiring temporary fixation because of their biodegradable properties. The use of biodegradable materials for temporary fixation eliminates the need for a removal surgery. The goal of this project was to provide proof of concept that AZ31, a magnesium alloy, is a viable option as a biodegradable alternative to stainless steel and titanium alloys. A 3D computer model of the elbow was developed from X-ray computed tomography (CT) scans. Finite element analysis was used to simulate forces on the fracture site with 316L, 6061 aluminum, and AZ31 fixation hardware. Displacement of the fracture site was analyzed for both materials. At 165N of tensile force, fracture displacement was 0.64mm and 0.66mm for 316L and AZ31 hardware, respectively. The data from the model was verified by subjecting a physical model of the fractured joint to tensile forces. Since the displacement produced by AZ31 is comparable to 316L, AZ31 may be a viable material for use in olecranon fracture fixation.

Acknowledgements

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1.0 Introduction

The elbow joint consists of three bones: the humerus, radius, and ulna, as shown in Figure 1. Many muscles originate or insert near the elbow, making it a common site for injury. Fractures of the elbow typically involve a part of the ulna known as the olecranon. These fractures may be caused by either direct or indirect contact, and may be treated with surgical or non-surgical techniques. The treatment depends on the severity of the fracture. Type II fractures are the most common elbow fractures and result in displacement of bone pieces.¹ These fractures are best treated with surgery. A common surgical technique for transverse olecranon fractures is tension band wiring (TBW).

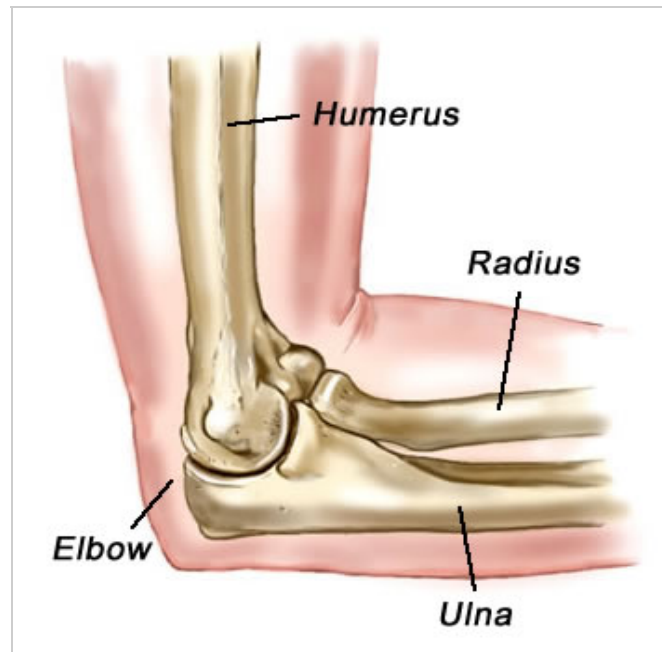


Figure 1: Lateral view of the bones in a normal elbow joint¹

Tension band wiring is a surgical technique that involves the use of two Kirschner (K) wires, or pins, and a tension band wire in the form of a figure eight to secure the bone. The tension band converts the triceps tensile forces on the posterior side of the olecranon into compression forces at the joint line.¹ The figure-eight wire loop lies on the posterior surface of the olecranon and serves as the tension band to convert the forces when tightened. The TBW technique is shown in Figure 2.

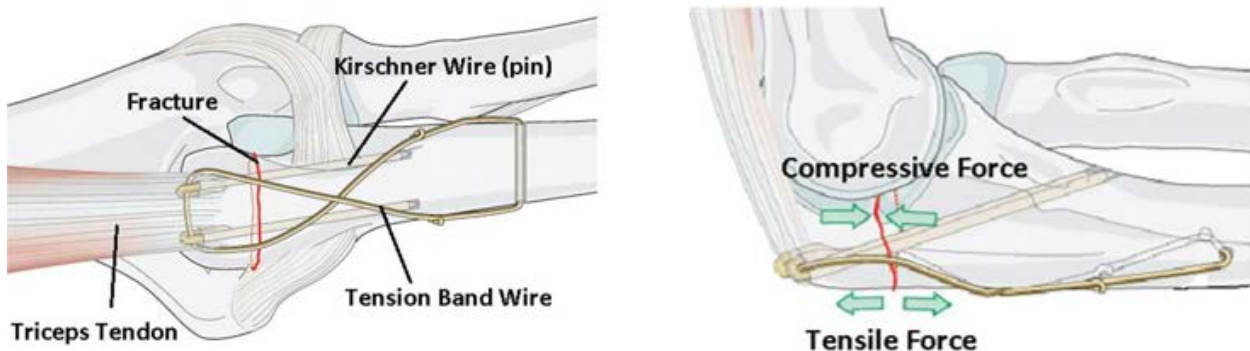


Figure 2: Bottom view of tension band wiring of olecranon fracture (left) Lateral view showing forces on fracture site (right)¹

Today, the pins and wires for tension band wiring are most commonly made out of 316L stainless steel. It takes about eight weeks for the fracture to heal completely. Tension band wiring (TBW) has been shown to be an effective surgical technique to produce favorable functional results regardless of fracture severity, with 85% of patients regaining very good function.² Tension band wiring requires intricate twisting of the wires, and the elbow joint itself is not uniform. Due to the great ductility and strength of 316L stainless steel, it is a favorable material for use in this surgical technique.³ After healing is complete, about 40-80% patients undergo a removal surgery due to discomfort caused by the pins and wires.⁴ This discomfort is a common complication of tension band wiring due to the prominence of the K-wires at the elbow. In some cases, this results in skin breakdown and infection, and the hardware must be removed.⁵ Another complication associated with stainless steel fixation hardware is stress shielding. Stress shielding occurs when an implant made of a material stronger than bone removes the normal stress from the bone. Since bone is stimulated to remodel and grow in response to applied load, a decrease in loading on the bone causes loss of bone density and may cause implant loosening.⁵

In recent years, biodegradable implants have been used for orthopedic applications where only temporary fixation is necessary.⁶ These materials maintain required strength for the duration of healing and eventually degrade completely. Biodegradable implants are designed to circumvent the disadvantages of permanent materials. Biodegradable materials currently used in orthopedics include polyglycolic acid (PGA) and polylactic acid (PLA).⁷ One biodegradable material that has been receiving increasing amounts of attention for use in medical applications is magnesium alloy. Compared to 316L stainless steel, magnesium and its alloys have many properties closer to those of bone, including density, compressive yield strength, elastic modulus, and fracture toughness, as shown in Table 1 below.

Table 1: Physical and mechanical properties of materials used in this study compared to those of natural bone^{8, 9, 10}

Material	Density (g/cm³)	Compressive Yield Strength (MPa)	Elastic Modulus (Gpa)	Fracture Toughness (MPam^{1/2})
Cortical Bone	1.8-2.1	130-180	3.0-20	3-6
316L SS	7.9-8.1	170-310	189-205	50-200
Mg	1.74-2.0	65-100	41-45	15-40
AZ31	1.5-1.95	138-262	42-47	12-18
6061Al	2.7	97-172	68-71.5	34-35

Due to the fact that the strength and elastic modulus of pure magnesium and AZ31 are closer to bone than those of 316L, there is little concern of stress shielding effects. In addition to its mechanical properties, magnesium is biocompatible. It is readily available in the human body and may promote bone cell attachment and tissue growth on the implants. Most importantly, magnesium alloys are biodegradable, being progressively absorbed by the body after healing is complete, eliminating the need for an implant removal surgery.¹¹

The purpose of this project is to provide proof of concept that AZ31 is a viable option as a biodegradable alternative to stainless steel and titanium alloys for tension band wiring of olecranon fractures. If successful for this application, magnesium alloys may be considered for other similar applications such as fixation of hand and wrist fractures using K-wires.¹²

2.0 Objectives

The overall objectives of this MQP are to:

- Understand olecranon fractures and the tension band wiring fixation technique
- Develop a 3D model of a fractured ulna fixed with tension band wiring and simulate the forces acting on the olecranon during healing
- Verify the results of the model experimentally with commercially available physical models of the joint
- Examine the feasibility of using magnesium (Mg) alloys, particularly AZ31, for tension band wiring of olecranon fractures

3.0 Methodology

3.1 Finite Element Model

CT scans of a healthy elbow were obtained (Worcester County Orthopedics, Worcester, MA). An example of a CT scan is shown in Figure 3. The CT scans were converted into a 3D computer model using Mimics software (Medical version 16).



Figure 3: CT scan image of a normal elbow joint

A transverse fracture was introduced into the olecranon of the computer ulna model. The holes, pins, and tension band wire were added to the model according to the tension band wiring procedure as stated by the Association for the Study of Internal Fixation (AOF).¹ The process of developing the model from CT scans to the final model with fracture and hardware is shown in Figure 4.

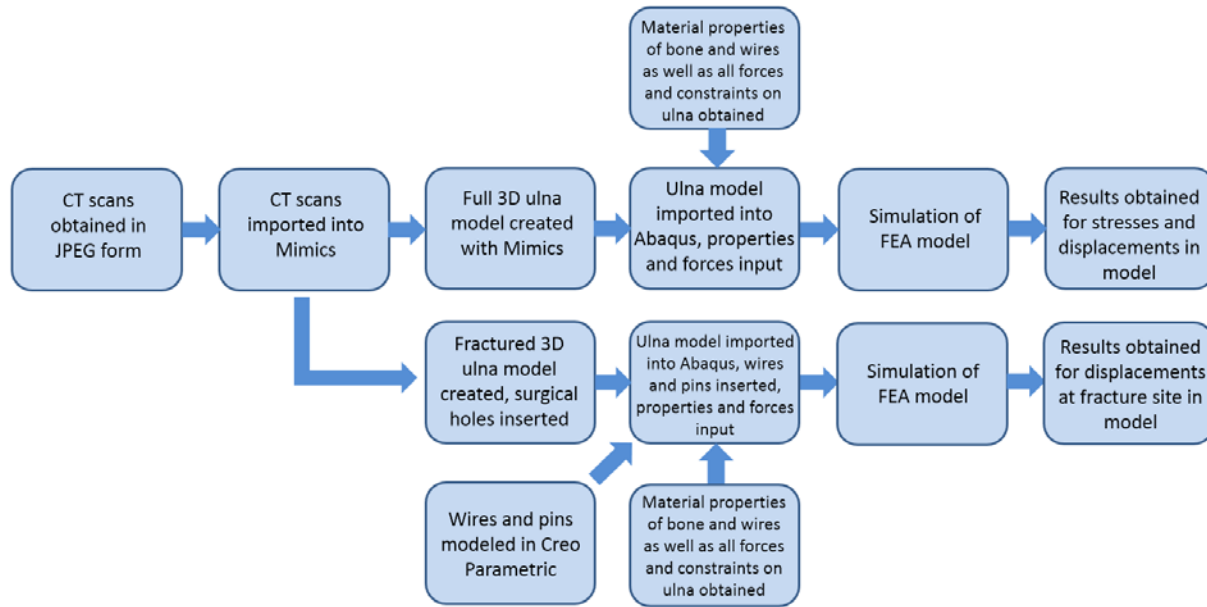


Figure 4: Flow chart showing the stages of conversion of the CT scan data to a finite element model system indicating the output from the model.

The finite element analysis (FEA) software Abaqus (Dassault Systemes version 6.13) was used to simulate *in vivo* forces acting on the ulna. The assumptions in the FEA model are shown in Table 2. The properties used for the materials in the model are shown in Table 1 and Table 3. The normal bone model was analyzed first to ensure the model would produce accurate values. Forces were applied to the top of the olecranon process to simulate the force exerted by the triceps.

Table 2: Assumptions in the Finite Element Analysis of 3D Computer Ulna Model

-	Bone is homogenous in material. Mechanical properties of cortical bone were obtained and carried through the model. Effects of marrow and porous regions of bone were not considered.
-	End of the model opposite the olecranon was held rigid. Forces from twisting of the wrist (which slightly moves ulna) were not considered.
-	Triceps force was assumed to be the only muscle force acting on the olecranon. A force from the humerus on the trochlear notch was considered. All other forces from muscles and ligaments were considered negligible.

A simulation software, OpenSim (version 3.1) is able to calculate forces exerted by specified muscles during motion. The properties used in the software model are normal cortical bone from 50th percentile anthropometric data. By measuring the force exerted by the triceps during a one-arm curl, it was calculated that the force exerted by the triceps is approximately 165N at 90° of flexion, which is the position of the arm during healing. This value is comparable to a similar study by Hammond et al, in which a 160N load was applied.¹³ The OpenSim model with the arm at 90° of flexion can be seen in Figure 5. The red lines represent the triceps and biceps muscles acting on the elbow joint.

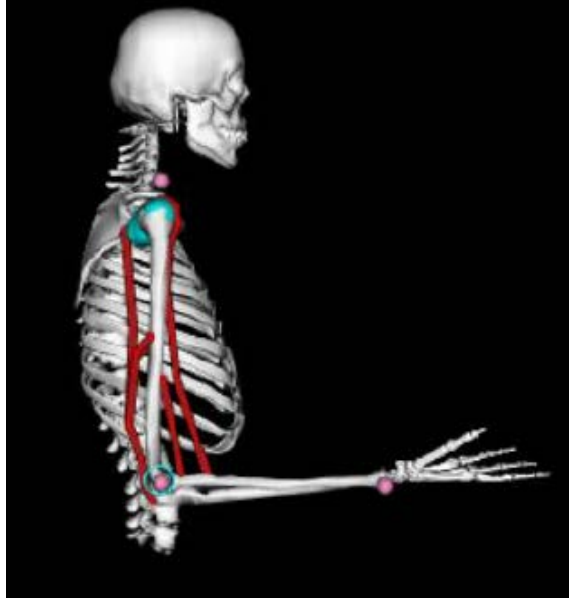


Figure 5: Image of OpenSim analysis of muscle forces acting on elbow joint with red lines representing muscle forces¹⁴

Forces lower and greater than 165N were also applied to the top of the olecranon to ensure that the fixation hardware would be able to withstand forces at different degrees of elbow flexion. These tests were performed for hardware with material properties of 316L SS, 6061 Al, and AZ31. 6061 Al was used for verification purposes of physical testing, as explained further in the following section. Since AZ31 has a lower strength than 316L and degrades, the pins and wires would need to be larger in diameter than the 316L hardware. Therefore, the 6061 Al pins and wire were larger in diameter to simulate the initial state of the AZ31 hardware. The diameters were proportional to the yield strength of the two materials. The 6061Al pins and wire were 2.4mm and 1.6mm in diameter. The 316L pins and wire were 1.6mm and 1.0mm in diameter respectively. After running the test for each force, the displacement at the fracture site was measured.

3.2 Physical Tensile Testing

In order to verify the data from the FEA model, physical models made with PVC were obtained (ERP#1004, Sawbones; Pacific Research Laboratories, Vashon, Washington). A tensile force was applied on the physical models and the fracture displacements were measured. The measured data were compared with the results from the FEA model. The materials used for the hardware were 316L SS and 6061Al. AZ31 is a heat treated alloy with relatively low ductility (19.7%).¹⁵ Thus it could not be twisted properly to produce the tension band wires at the joint. Therefore, an aluminum alloy (6061) with better ductility but similar mechanical properties to AZ31, as shown in Table 1, was chosen for the tension band wire. However, additional work with annealed AZ31 wire will be conducted to examine the performance of these alloys.

An initial fracture was introduced on the ulna models at the common fracture site. Surgical holes were drilled into the ulna models, and the pins and wires were then inserted according to the AOF procedure for tension band wiring. As with the FEA, the 6061Al pins and wire were larger in diameter than the 316L hardware. The 6061Al pins and wire were 2.4mm and 1.6mm in diameter. The 316L pins and wire were 1.6mm and 1.0mm in diameter respectively. Tensile testing was performed on each ulna model using an Instron model 4201. Tensile force was applied to the pins in the bone models to simulate the force from the triceps. The prepared ulna models and the experimental setup for tensile testing are shown in Figure 6.

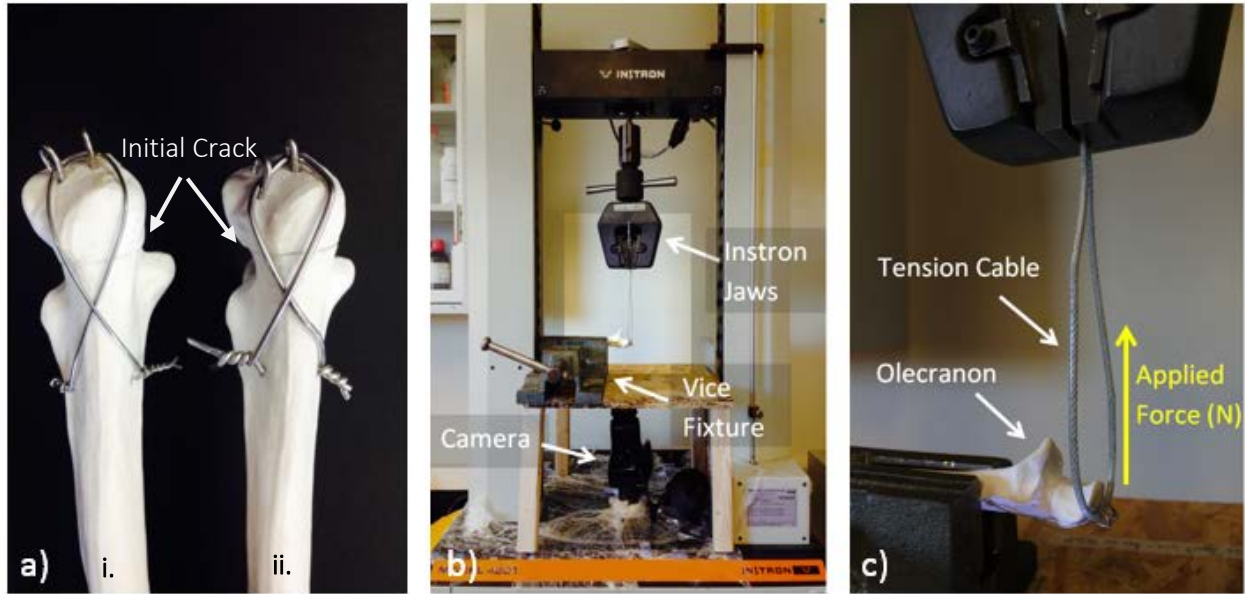


Figure 6: a) PVC ulna models with 316L hardware (i.) and 6061Al hardware (ii.) shown fixating the initiated cracks b) Instron model 4201 testing apparatus c) Close-up of ulna model during tensile testing

The force was applied at a strain rate of 20mm/min until a force of approximately 400N was reached. A camera positioned under the bone was used to take photographs of the fracture site every two seconds throughout the test. These photographs were used to measure the displacement of the fracture as greater force was applied.

According to surgical practice, fracture displacements of less than 2mm are determined to be insignificant, while displacements of greater than 2mm are considered a fracture fixation failure.^{13,16} The resulting fracture displacements measured from the FEA and physical tensile testing were compared.

4.0 Results

This work is prepared as a submission for publication in the journal *Orthopedics*. Most of the results are presented in the journal article, which is included in the following sections. The salient results are briefly discussed in this section. Further, this work was presented at the *Northeast Bioengineering Conference*, Northeastern University, Boston, MA April 26, 2014. This work will also be presented in the *Next Generation Biomaterials symposium* at the Materials Science & Technology conference in Pittsburgh, PA October 12-16, 2014. The abstracts submitted to these conferences are included in Appendix A.

An example of the FEA displacement distribution for the model with AZ31 hardware with 100N and 220N of tensile force applied to the olecranon is shown in Figure 7. These forces were chosen to demonstrate the fracture displacement at a force less than and greater than the triceps force of 165N. In the figures, U represents displacement in meters.

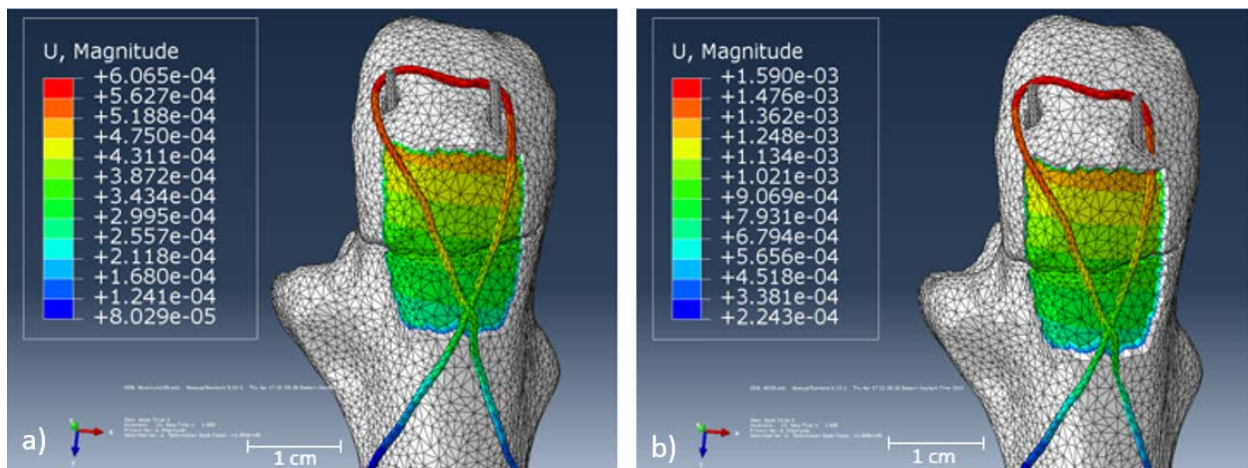


Figure 7: Calculated displacement (U) distribution across the fractured joint when AZ31 wire is used for tension band wiring in the FEA model with a) 100N triceps force and b) 220N triceps force.

The FEA results show nearly identical displacements for 6061Al and AZ31 hardware, as shown in Figure 8. This provides evidence that the two materials are similar in mechanical and physical properties, and 6061Al may be used to simulate AZ31 for physical testing.

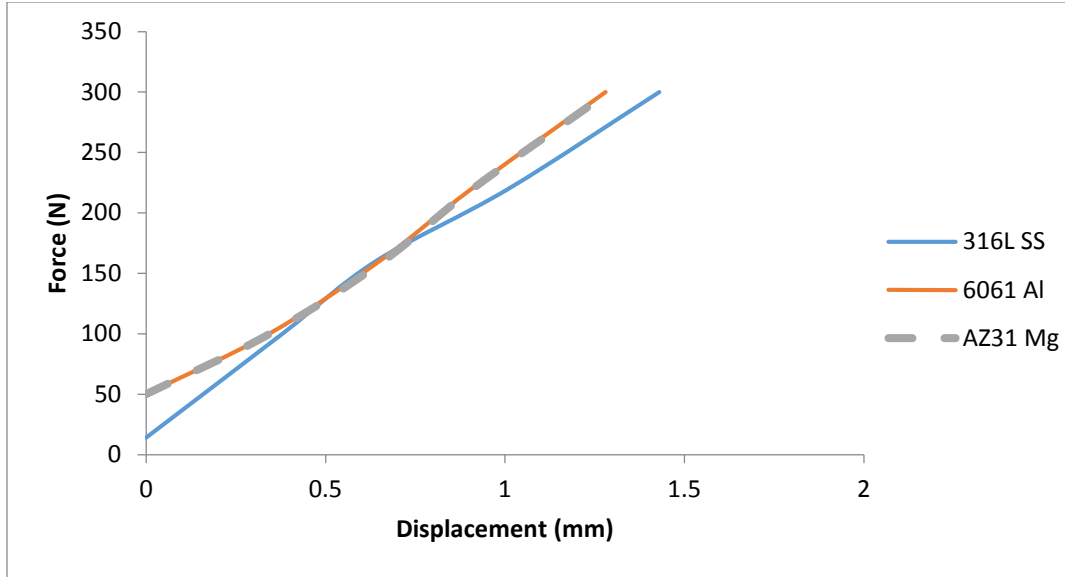


Figure 8: Variation of applied force with displacement at the fracture site calculated from the FEA model for various tension band materials

The displacements from the physical testing were measured from the photographs taken throughout testing. Examples of the photographs taken at 0N force and 220N force for 6061Al and 316L are shown in Figure 9.

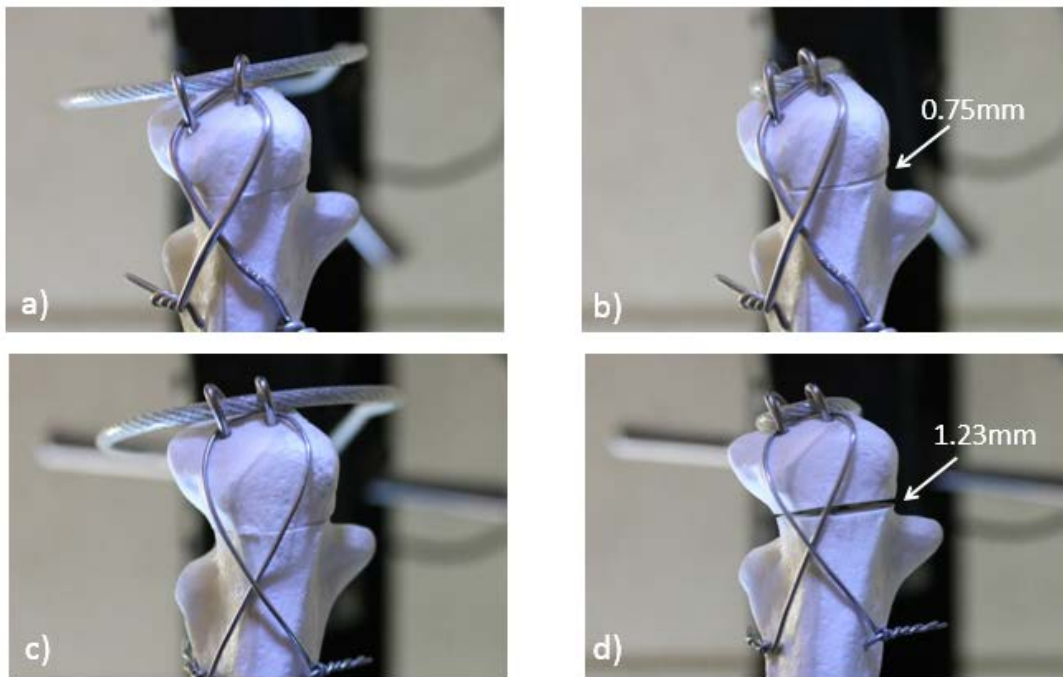


Figure 9: Sequential photographs showing the displacement at the joint for a force of 220N for 6061Al (b) and 316L stainless steel (d). The initial position of the fracture site are shown for 6061Al (a) and 316L (c)

The physical tensile testing of the ulna models with 316L and 6061Al produced results similar to those from the FEA testing, as shown in Figure 10. This provides confirmation that the FEA results are accurate

for 316L and 6061Al, and therefore the FEA results for AZ31 are also accurate. The overall displacement data obtained from the FEA model and tensile testing are included in Appendix B.

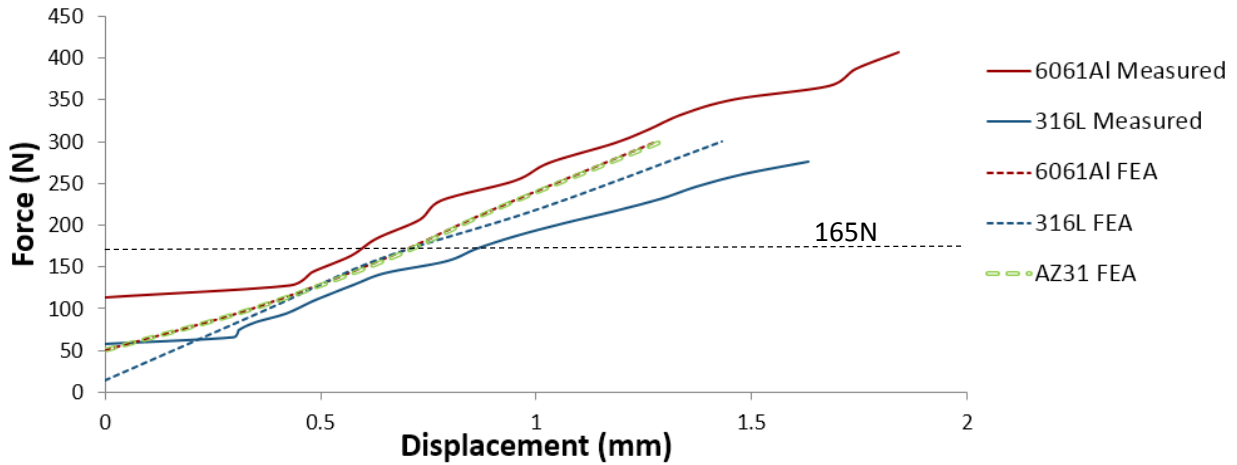


Figure 10: Variation of fracture displacement with applied tensile force. The calculated values from the FEA model (dashed lines) and the experimentally measured data (solid lines) are shown for comparison.

As shown by the FEA results in Figure 9, the three materials exhibit similar displacements at 165N. This suggests that the materials have similar strengths and maintain the same level of fixation when the elbow is at 90° of flexion, which is the position of the elbow throughout the healing process. The data for both finite element testing and physical testing show that even at 300N of force, the fracture displacement remains within the acceptable range for displacement during healing.

5.0 Journal Article

Use of Magnesium Alloys in Tension Band Wiring of Olecranon Fractures

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Abstract

Fractures of the olecranon are common elbow injuries that represent about 10% of upper extremity lesions. Tension band wiring is a surgical technique to fix olecranon fractures. This technique involves inserting two pins and a tension band wire in a figure eight configuration to convert the tensile forces affecting the fracture into compressive forces. After the bone is healed, the hardware is no longer necessary and is typically removed through a second surgery in response to the pain and discomfort it causes. Currently, the pins and wires are primarily made of 316L stainless steel. Magnesium alloys have recently been recognized for their potential use in orthopedic applications requiring temporary fixation because of their biodegradable properties. The use of biodegradable materials for temporary fixation eliminates the need for a removal surgery. The goal of this project was to provide proof of concept that AZ31, a magnesium alloy, is a viable option as a biodegradable alternative to stainless steel and titanium alloys. A 3D computer model of the elbow was developed from X-ray computed tomography (CT) scans. Finite element analysis was used to simulate forces on the fracture site with 316L, 6061 aluminum, and AZ31 fixation hardware. Displacement of the fracture site was analyzed for both materials. At 165N of tensile force, fracture displacement was 0.64mm and 0.66mm for 316L and AZ31 hardware, respectively. The data from the model was verified by subjecting a physical model of the fractured joint to tensile forces.

1.0 Introduction

The elbow joint consists of three bones: the humerus, radius, and ulna. Many muscles originate or insert near the elbow, making it a common site for injury. Fractures of the elbow typically involve a part of the ulna known as the olecranon. These fractures may be caused by either direct or indirect contact, and may be treated with surgical or non-surgical techniques. The treatment depends on the severity of the fracture. Type II fractures are the most common elbow fractures and result in displacement of bone pieces. These fractures are best treated with surgery. A common surgical technique for transverse olecranon fractures is tension band wiring (TBW).

Tension band wiring is a surgical technique that involves the use of two Kirschner (K) wires, or pins, and a tension band wire in the form of a figure eight to secure the bone. The tension band converts the triceps tensile forces on the posterior side of the olecranon into compression forces at the joint line.¹ The figure-eight wire loop lies on the posterior surface of the olecranon and serves as the tension band to convert the forces when tightened. The surgery begins by drilling a 2mm hole into the bone 40mm distal to the fracture site and 5mm from the posterior cortex to prepare for insertion of the wire. Using forceps to reduce the fracture, the two 1.6mm K-wires are drilled through the triceps tendon and the head of the olecranon medially, aimed toward the anterior cortex. The pins are then cut and the ends are folded over. These pins are used for extra support and stabilization of the elbow. The 18 gauge (1.0-1.2mm) tension band wire is then looped through the drilled hole and the loops of the K-wires in a figure-eight configuration and tightened simultaneously, as shown in Figure 1.¹

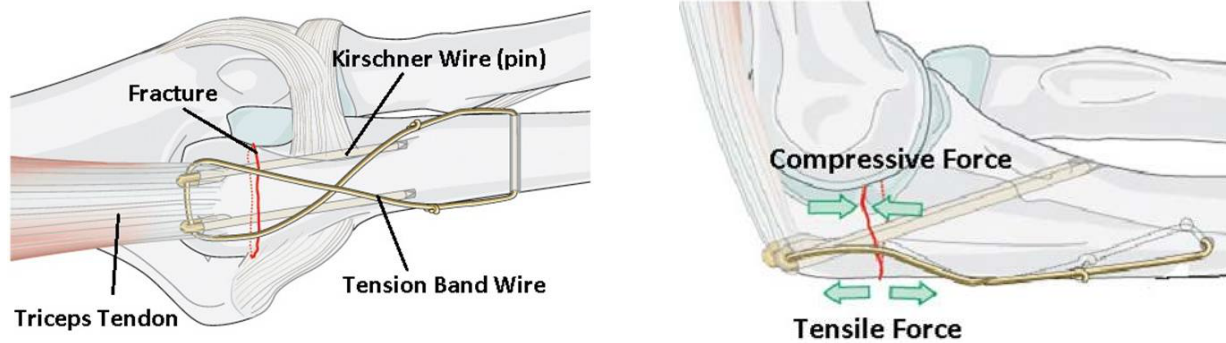


Figure 1: Bottom view of tension band wiring of olecranon fracture (left) Lateral view showing forces on fracture side (right)¹

Today, the pins and wires for tension band wiring are most commonly made out of 316L stainless steel. It takes about eight weeks for the fracture to heal completely. A study by Holdsworth et al has shown tension band wiring to be an effective surgical technique to produce favorable functional results regardless of fracture severity, with 85% of patients regaining very good function.² Tension band wiring requires intricate twisting of the wires, and the elbow joint itself is not uniform. Due to the great ductility and strength of 316L stainless steel, it is a favorable material for use in this surgical technique.³ After healing is complete, about 40-80% patients undergo a removal surgery due to discomfort caused by the pins and wires.⁴ This discomfort is a common complication of tension band wiring due to the prominence of the K-wires at the elbow. In some cases, this results in skin breakdown and infection, and the hardware must be removed.⁵ Other complications associated with stainless steel and titanium alloy implants include stress shielding and implant loosening.²

In recent years, biodegradable implants have been used for orthopedic applications where only temporary fixation is necessary.⁶ These materials maintain required strength for the duration of healing, and eventually degrade completely. Biodegradable implants are designed to circumvent the disadvantages of permanent materials. One biodegradable material that has been receiving increasing amounts of attention for use in medical applications is magnesium alloy. Compared to 316L stainless steel, magnesium alloys exhibit properties closer to those of bone. Table 1 shows a comparison of mechanical properties between cortical bone and multiple materials used in this study including AZ31, a magnesium alloy commonly used in orthopedic studies.

Table 1: Physical and mechanical properties of materials used in this study compared to those of natural bone^{7,8,9}

Material	Density (g/cm ³)	Compressive Yield Strength (MPa)	Elastic Modulus (Gpa)	Fracture Toughness (MPam ^{1/2})
Cortical Bone	1.8-2.1	130-180	3.0-20	3-6
316L SS	7.9-8.1	170-310	189-205	50-200
Mg	1.74-2.0	65-100	41-45	15-40
AZ31	1.5-1.95	138-262	42-47	12-18
6061Al	2.7	97-172	68-71.5	34-35

As shown in the Table 1, stainless steel has a significantly higher elastic modulus and yield strength than natural cortical bone. Although this material exhibits excellent strength for fracture fixation, the vast difference in strength may result in stress shielding, which could lead to bone loss and implant loosening. The properties of pure magnesium and AZ31 are closer to bone than those of 316L, reducing the chance of stress shielding effects. In addition to its mechanical properties, magnesium is biocompatible. It is readily available in the human body and may promote bone cell attachment and tissue growth on the implants.

Most importantly, magnesium alloys are biodegradable, being progressively absorbed by the body after healing is complete, eliminating the need for an implant removal surgery.¹⁰

The purpose of this project is to provide proof of concept that AZ31 is a viable option as a biodegradable alternative to stainless steel for tension band wiring of olecranon fractures. If successful for this application, magnesium alloys may be considered for other similar applications such as fixation of hand and wrist fractures using K-wires.¹¹

2.0 Materials and Methods

2.1 Modeling of the Joint

CT scans of a healthy elbow were obtained (Worcester County Orthopedics, Worcester, MA) to be converted into a 3D computer model of an ulna with a transverse olecranon fracture. An example of a CT scan image of a normal elbow joint is shown in Figure 2.



Figure 2: CT scan image of a normal elbow joint without fracture

The CT scans were converted into a 3D computer model using the software package Mimics (Medical version 16). The conversion process began by specifying the distance between each scan (1mm, based on information on the CT scans). This allowed for a bone model of accurate proportions to be produced. It was assumed that the ulna was the only bone of the elbow needed to model, as forces acting from the other bones could be simulated using finite element analysis software. The bone was modeled as a homologous solid assuming uniform properties of cortical bone. The 3D model was modified using the Mimics software to replicate the ulna with a transverse olecranon fracture. Two 2mm holes were then created at the location where Kirschner wires would be inserted during an olecranon fracture. A 2mm hole was also introduced approximately 40mm distal to the fracture site to allow for a wire to be inserted. The sizes, locations, and orientations of these holes were determined according to the Association for the Study of Internal Fixation (AOF) procedure for tension band wiring.¹ The steps of developing the 3D model are illustrated in parts A, B, and C of Figure 3.

The simple 3D model was then imported into the finite element analysis software Abaqus (Dassault Systemes version 6.13). The software package Creo Parametric (version 2.0) was used to create the Kirschner and tension band wires to be used in conjunction with the 3D ulna model created in Mimics. The

fractured 3D ulna model was first imported into Creo Parametric. Using the Freeform tool, a feature that allows the user to create solid geometries with a clay-form type interface, the Kirshner and tension band wires were created directly on top of the ulna model. This allowed the wires to fit closely to the contours of the bone. These wires were imported into Abaqus and assembled with the fractured ulna in order to create the final model, as shown in part D of Figure 3. 316L stainless steel, AZ31, and 6061Al were each tested as materials for the hardware. 6061Al was used for verification purposes of physical testing, as explained further in the following section. Since AZ31 has a lower strength than 316L and degrades, the pins and wires would need to be larger in diameter than the 316L hardware. Therefore, the 6061Al pins and wire were larger in diameter to simulate the initial state of the AZ31 hardware. The 6061Al pins and wire were 2.4mm and 1.6mm in diameter. The 316L pins and wire were 1.6mm and 1.0mm in diameter respectively.

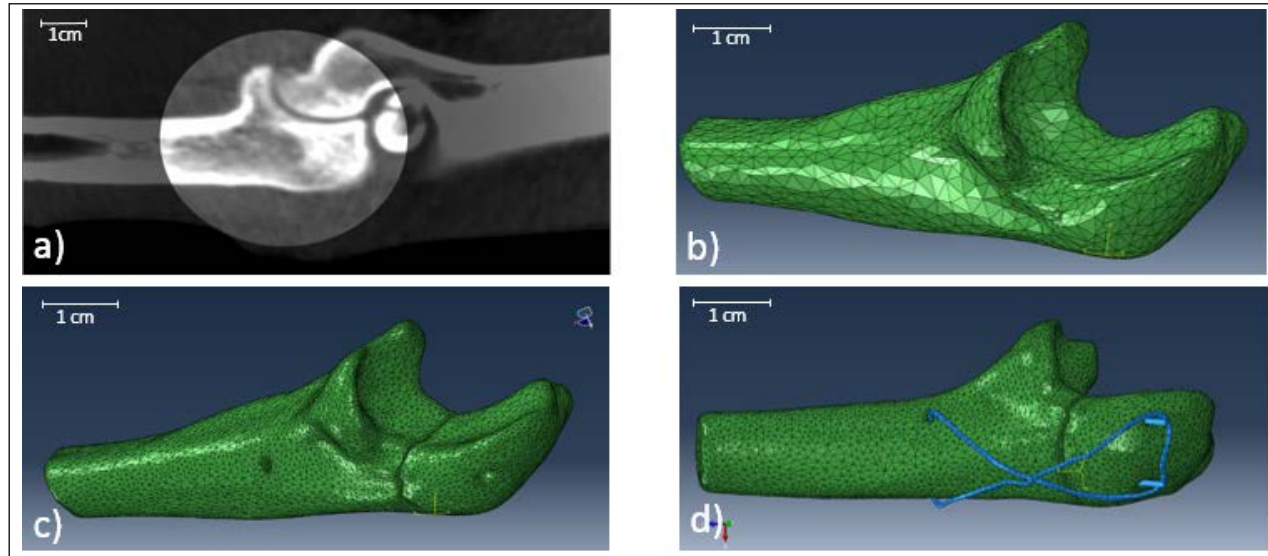


Figure 3: Development of the model: a) CT scan image of a normal elbow joint b) Normal ulna model from CT scans in Abaqus c) Fractured ulna with holes for TBW hardware d) Ulna model with TBW hardware

Tests were developed in Abaqus to simulate *in vivo* forces on the ulna, first with the natural bone without fracture. Concentrated forces were positioned at the insertion point of the triceps at the top of the olecranon process as well as at the contact point of the humerus and ulna. The forces were varied and analyzed for different degrees of elbow flexion, as determined by the simulation software OpenSim (version 3.1), with a triceps force of 165N at 90° of flexion. This value is comparable to a similar study by Hammond et al, in which a 160N load was applied.¹² The long bone portion of the ulna was fixed to prevent movement due to forces. For the model of the fractured ulna, materials properties of 316L SS, 6061Al, and AZ31 were applied to the tension band and K-wires. Local displacement was measured at certain points on the model and compared in order to see the difference between a natural ulna without fracture, a fractured ulna with the different hardware materials. Figure 4 shows the model system used in Abaqus.

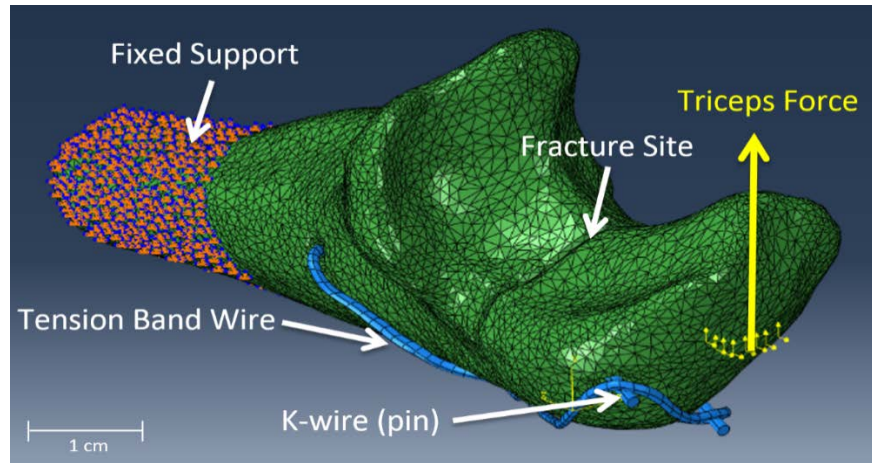


Figure 4: Image of model system used for analysis in Abaqus

2.2 Physical Testing

In order to verify the data from the FEA model, physical models made with PVC were obtained (ERP#1004, Sawbones; Pacific Research Laboratories, Vashon, Washington). While these synthetic bone models do not have the exact properties of cortical bone, they are commonly used in preliminary biomechanical testing as the properties are similar and they allow for reproducibility of tests.¹³ A tensile force was applied on the physical models and the fracture displacements were measured. The measured data were compared with the results from the FEA model. The materials used for the hardware were 316L SS and 6061Al. AZ31 is a heat treated alloy with relatively low ductility (19.7%).¹⁴ Thus it could not be twisted properly to produce the tension band wires at the joint. Therefore, an aluminum alloy (6061) with better ductility but similar mechanical properties to AZ31, as shown in Table 1, was chosen for the tension band wire. However, additional work with annealed AZ31 wire will be conducted to examine the performance of these alloys.

The ulna models were prepared according to the AOF procedure for tension band wiring.¹ Each model was sawed to imitate a simple transverse olecranon fracture. The first ulna model was inserted with two 316L SS pins 1.6mm in diameter. A stainless steel wire of 1.0mm diameter was arranged in a figure-eight fashion and simultaneously tensioned by two pliers. This process was repeated in the second ulna model using 6061Al pins and wire. As in the FEA testing, the 6061Al pins and wire were 2.4mm and 1.6mm in diameter. The 316L pins and wire were 1.6mm and 1.0mm in diameter respectively. The fractured ulna models with the 316L and 6061Al fixation hardware can be seen in Figure 5.

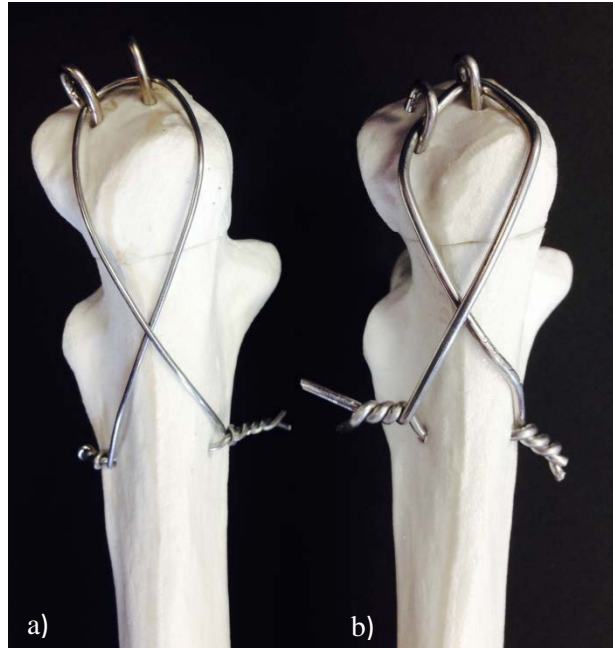


Figure 5: Portion of the physical ulna model showing the fracture site and the position of the tension band pins and wires (a) 316L and (b) 6061Al

Tensile testing was performed on each ulna model using an Instron model 4201. A fixture assembly was created to hold the ulna allow space for a camera, as shown in Figure 6. A cable was looped through the pins in the ulna and connected to the Instron machine in order to simulate the force from the triceps tendon acting on the olecranon process. The bone was secured with a vice clamp. A camera was positioned under the apparatus to take pictures of the fracture site every two seconds during the tensile test. The fracture site of each ulna was measured before the testing began and again once the testing was complete using the pictures.

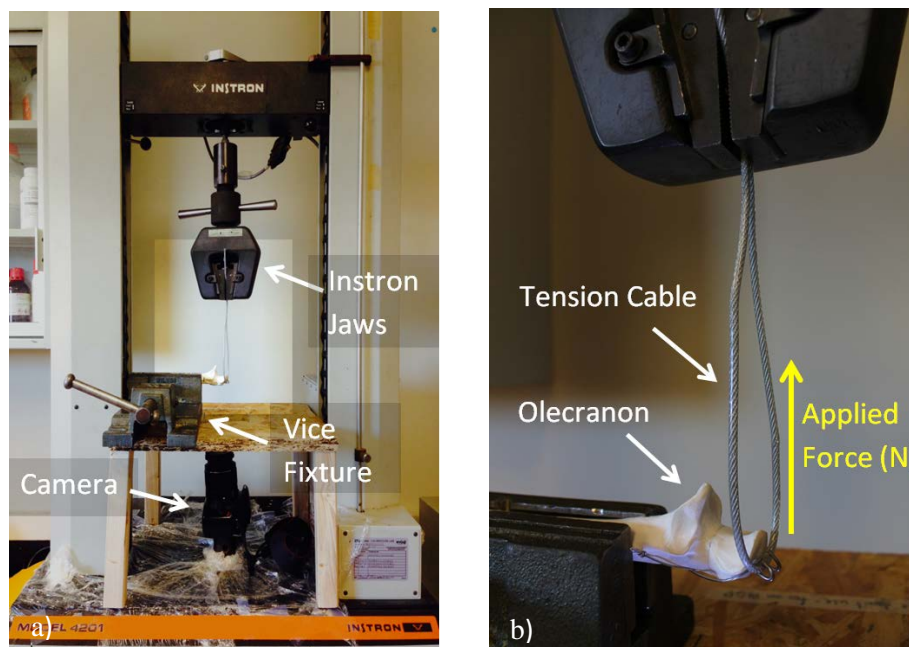


Figure 6: Instron model 4201 testing apparatus (a) and close-up of ulna with TBW hardware during testing (b)

The Instron machine applied a tensile load to the ulna at a strain rate of 20mm/min until a force of approximately 400N was reached, much greater than the triceps force at that orientation. The displacement at the fracture site was measured using the photographs taken throughout the testing. Displacements of less than 2mm were determined to be insignificant separation during bone healing.^{12,15} Displacements greater than 2mm were considered a fixation failure.^{12,15} The results from FEA and physical tension testing were compared.

3.0 Results

3.1 Finite Element Analysis

The normal 3D ulna model without a fracture was first tested with a triceps force of 165N, the average force exerted on the olecranon by the triceps at 90° of flexion. Maximum Von Mises stresses were then obtained for the entire ulna model. It was found that the average Von Mises stresses with no other external forces applied on the ulna were around 520KPa. According to a study in which ulna (and specifically trochlear notch) stresses were measured as force was incrementally applied until failure, stresses calculated for the ulna at a resting 90° flexion angle (165N of triceps force) were found to be approximately 500KPa.¹⁶

This result showed that the Von Mises stresses of the computer ulna model were similar to those of natural ulnas under the same force in the body. In the computer model, the bone was considered homogenous; differing properties due to porosity in parts of the bone as well as bone marrow were not considered. This was proved acceptable as the stresses matched those of a real ulna quite well.

The computer model of the fractured ulna with hardware was tested with various triceps forces for 316L SS, 6061 Al, and AZ31 Mg. The triceps forces applied ranged from 0N to 300N. Although the max triceps force at 90° flexion while at rest is 165N, applying larger forces ensured that the fracture could still be healed in case the patient lifted objects, or performed any activities that would cause a larger force to be exerted. The materials mentioned, 316L SS, 6061 Al, and AZ31 Mg, were analyzed for both the pins and tension band wire. The displacement at the underside of the fracture site was measured. A fracture displacement of 2mm or greater during fixation represents a fixation failure.^{12,15} Figure 7 shows resulting displacements, as measured in meters, from the FEA model for both Aluminum 6061 and Magnesium AZ31 at 165N of triceps force.

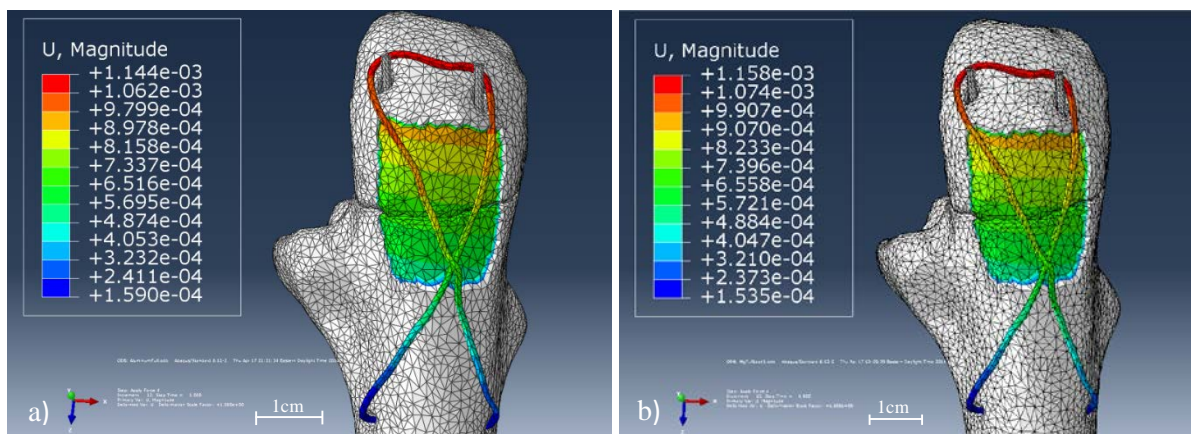


Figure 7: Picture of FEA displacement results, in meters, for 6061 Al (a) and AZ31 Mg (b) at 165N of triceps force

The resulting displacements with changing force calculated from the FEA model for each material are shown in Figure 8.

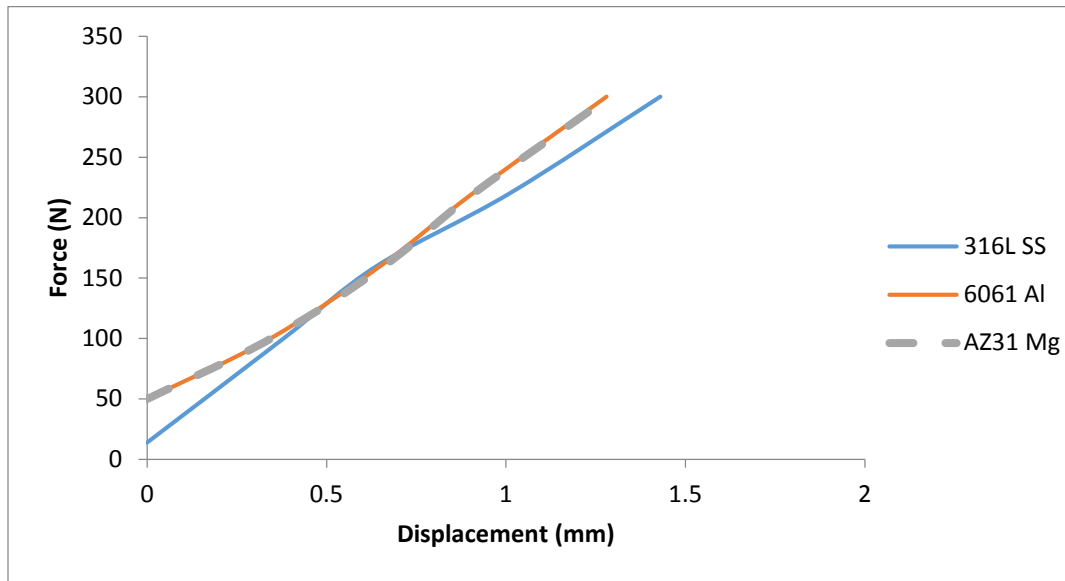


Figure 8: Variation of applied force with displacement at the fracture site calculated from the FEA model for various tension band materials.

As can be seen by the Figure 8, the 6061Al exhibited similar displacement values as AZ31 Mg. Due to the very similar displacement results as well as the similar mechanical properties of 6061 Al and AZ31 Mg, 6061 Al could be used to simulate magnesium in physical testing.

The finite element analysis shown in Figure 8 produced higher displacements for 316L than both 6061 Al and AZ31 Mg. All wires were tested at various forces between 0N and 300N. Despite 316L SS producing larger displacements than the other wires, it was still within the acceptable fracture fixation range, having displacements of less than 2mm even at 300N of applied triceps force. The displacements for each wire were also almost equal at 165N of applied triceps force (the average max force when the elbow is resting at 90° flexion). All types of wire had approximately a 0.7mm displacement at 165N of triceps force. According to these tests, 6061Al and AZ31 Mg have the mechanical strength needed to fix the fracture when initially inserted into the bone.

3.2 Physical Testing

Physical testing of the ulna models was performed to validate the model and verify that AZ31 may be a viable material substitution over 316L for olecranon fracture fixation. The results from the physical testing were compared with the FEA results in Figure 9.

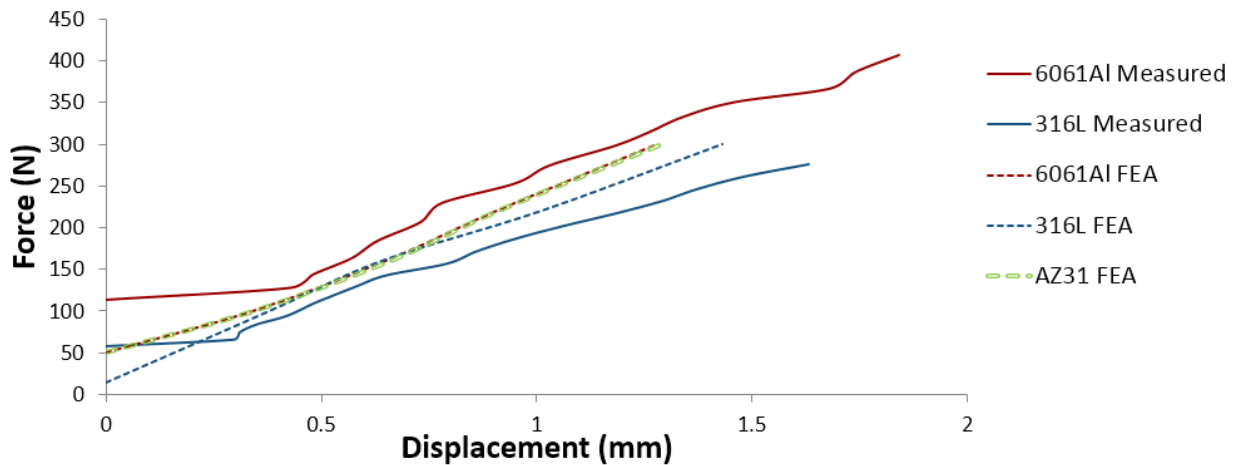


Figure 9: Force vs. Displacement graph comparing FEA results and physical tensile testing results for each material

As shown in Figure 9, there is a general agreement between the FEA generated data and the physical measurements. This provides confirmation that the FEA results are accurate for 316L and 6061Al, and therefore the FEA results for AZ31 are also accurate.

4.0 Conclusions

Olecranon fractures are commonly fixed with tension band wiring and heal within eight weeks. The FEA results show that at 165N of triceps force, which is the force exerted by the triceps at 90° of elbow flexion, the 316L, 6061Al, and AZ31 hardware produced similar fracture displacement. The physical testing of 316L and 6061Al hardware produced fracture displacements similar to those from FEA. The AZ31 pins and wires need to have diameters larger than 316L SS to match strength (2.4mm pins, 1.6mm wire vs. 1.6mm pins, 1.0mm wire). Using hardware with a larger diameter was determined by an orthopedic surgeon to not have an effect on the surgical technique or healing of the fracture. While the data suggests AZ31 may be a viable material for tension band wiring of olecranon fractures, the ductility must be improved for intricate twisting of the tension band wire, and the degradation of the alloy must be examined. The use of AZ31 or other Mg alloys for tension band wiring of olecranon fractures would eliminate the need for a second surgery to remove the hardware, which would be both safer and less costly for the patient. If successful, Mg alloys could be used for fixation of other fractures using similar hardware, such as hand or wrist fractures.

5.0 Acknowledgements

The authors would like to thank Philip Lahey, IV, M.D., Worcester County Orthopedics, for his advice and resources. The authors would like to express deep gratitude to Professor Karen Troy and Joshua Johnson, Department of Biomedical Engineering, Gateway Park, WPI, Worcester, MA for their extensive assistance in using Mimics and Abaqus.

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6.0 Conclusions and Recommendations

The FEA results show that at 165N of triceps force, which is the force exerted by the triceps at 90° of elbow flexion, the 316L, 6061Al, and AZ31 hardware produced similar fracture displacement. The physical testing of 316L and 6061Al hardware produced fracture displacements similar to those from FEA. The AZ31 pins and wires need to have diameters larger than 316L SS to match strength (2.4mm pins, 1.6mm wire vs. 1.6mm pins, 1.0mm wire). Using hardware with a larger diameter was determined by an orthopedic surgeon to not have an effect on the surgical technique or healing of the fracture. The use of AZ31 or other Mg alloys for tension band wiring of olecranon fractures would eliminate the need for a second surgery to remove the hardware, which would be both safer and less costly for the patient. While the data suggests AZ31 may be a viable material for tension band wiring of olecranon fractures, the ductility must be improved for intricate twisting of the tension band wire, and the degradation of the alloy must be examined. If successful, Mg alloys could be used for fixation of other fractures using similar hardware, such as hand or wrist fractures.

The Instron tensile testing should be performed using AZ31 pins and wires. The AZ31 hardware should be degraded in phosphate buffer solution for eight weeks, performing the tensile test every two weeks to measure the effects of degradation on the strength of AZ31. Further testing to perform includes using elbow cadavers with triceps and AZ31 hardware.

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8.0 Appendix A

Abstract Submitted to the 2014 Northeast Bioengineering Conference

Fractures of the olecranon are common elbow injuries. Tension band wiring is a surgical technique to fix olecranon fractures. This technique involves inserting two pins and a tension band wire in a figure eight configuration to convert the tensile forces affecting the fracture into compressive forces. After the bone is healed, the hardware is no longer necessary and is typically removed through a second surgery in response to the pain and discomfort it causes. Currently, the pins and wires are primarily made of stainless steel or titanium alloys. Magnesium alloys have recently been recognized for their potential use in orthopedic applications requiring temporary fixation because of their biodegradable properties. The use of biodegradable materials for temporary fixation eliminates the need for a removal surgery. The goal of this project is to provide proof of concept that AZ31, a magnesium alloy, is a viable option as a biodegradable alternative to stainless steel and titanium alloys. A 3D computer model of the elbow was developed from X-ray computed tomography (CT) scans. The model was evaluated using finite element analysis. Stainless steel and AZ31 properties were simulated in the model to determine the ability of magnesium to withstand stresses needed to fix the olecranon properly. The effects of degradation on the mechanical properties of AZ31 were analyzed in vitro using simulated body fluid and a 3D printed model of the elbow. Analysis of the results suggested that AZ31 has potential to be a viable material that can be used in olecranon fracture fixation.

Abstract Submitted to the 2014 Materials Science & Technology Next Generation Biomaterials Symposium

Fractures of the olecranon are common elbow injuries and represent about 10% of the upper extremity lesions. Surgical fixation of this fracture through tension band wiring involves inserting two 316L or Ti alloy pins and a tension band wire in a figure eight configuration. The feasibility of using biodegradable AZ31 magnesium alloy for this application is examined. A 3D computer model of the elbow was developed from X-ray CT scans. The model was evaluated using finite element analysis. The ability of magnesium to withstand stresses needed to fix the olecranon properly was evaluated and compared with that of 316L. A 3D printed model of the elbow was used to verify the results from the FEM model. The data suggest that AZ31 has the potential to be a viable material that can be used in olecranon fracture fixation.

9.0 Appendix B

Measured Instron Data for Aluminum 6061 (1.6mm) and Stainless Steel 316L (1.0mm) can be found in the attached Microsoft Excel Spreadsheet titled Measured_Instron_Data.xlsx.